

# REQUEST FOR EXPEDITED PROSECUTION:

## RESPONSE AFTER FINAL

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of ) Examiner: Scott David Priebe  
Robert J. Levy et al. ) Art Unit: 1633  
Serial No. 10/656,068 ) Our File No: CHOP.0100.1  
Filed: September 5, 2003 )  
For: "Methods and Compositions )  
for Enhancing the )  
Delivery of a Nucleic )  
Acid to a Cell" )

### REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §1.114

The June 1, 2007 Advisory Action has been carefully reviewed. In view of the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three months was set forth in the February 7, 2007 Final Official Action. Therefore, the initial due date for response was May 7, 2007. Accordingly, a petition for a 3 month extension is presented with this response, which is being filed within the three month extension period. Applicants previously paid the fee for a one month extension of time with the May 14, 2007 Official Action response.

The present remarks are being filed, along with the remarks and amendments submitted in the May 14, 2007 Official Action response, as part of the submission required under 37 C.F.R. §1.114, in connection with the Request for Continued Examination, which is submitted concurrently herewith.

The Examiner has indicated in the June 1, 2007 Advisory Action that the amendments submitted with the May 14,

2007 Official Action response will not be entered because they allegedly raise new issues that would require further consideration and/or search and they allegedly raise the issue of new matter.

Specifically, with regard to the new matter rejections of claims 68-70, the Examiner contends that Applicants failed to provide an authority to support the position that it is improper to limit an application only to the preferred embodiment. Applicants respectfully refer the Examiner to In re Goffe, 191 USPQ 429 (CCPA 1976), which states that:

For all practical purposes, the Board would limit Appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found to work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

As stated in the May 14, 2007 Official Action response, the instant specification clearly teaches at page 14, lines 24-29 that the collagen is denatured and that any type of collagen may be used. Example I demonstrates the denaturation of collagen by boiling bovine type I collagen in an acidic environment. While the specific example teaches that the collagen was boiled in acidic conditions for one hour, the length of time can be varied by a skilled artisan so long as denaturation of the collagen occurs, as required by the instant specification at page 14, lines 24-29.

Inasmuch as the specification expressly states that the collagen can be any type of collagen, the new matter rejection of claims 67-70 based on the collagen recited, clearly cannot be reasonably maintained. Furthermore, the new matter rejection based on the reaction conditions is untenable in view of 1) the disclosure that the collagen is denatured

(page 14, lines 24-29); 2) the exemplification of denaturation by boiling in acidic conditions (page 28, line 10-11); and 3) the disclosure at page 27, lines 13-16 that the Examples should be construed to encompass any and all variations. Therefore, withdrawal of the new matter rejections is respectfully requested.

As to the 35 U.S.C. §102/103 rejections, Applicants continue to respectfully disagree with the Examiner's position with regard to the amount the court's reliance in Rapoport v. Demont on the timing of the administration of the compound for the reasons of record. With regard to In re Marshall, the Examiner continues to maintain the position that the "distinguishing feature was the required dosage of the compound." Applicants continue to disagree with the Examiner for the reasons of record. Moreover, the court in In re Marshall unequivocally states that an "accidental or unwitting duplication of an invention cannot constitute an anticipation." The court did not reach this conclusion de novo, but rather was citing In re Felton, 484 F.3d 495 (CCPA 1973) as precedent. As indicated in the July 21, 2006 Official Action, this conclusion is also consistent with the reasoning of the U.S. Supreme Court in Tilghman v. Proctor. Here, the references cited by the Examiner wholly fail to teach or suggest that denatured collagen or a peptide thereof enhances the delivery of a nucleic acid molecule. Furthermore, the cited references provide other explanations such as cell adhesion for utilizing gelatin (see July 21, 2006 Official Action response).

In view of the foregoing, Applicants submit that the 35 U.S.C. §102/103 rejections are untenable and withdrawal of these rejections is respectfully requested.

#### **CONCLUSION**


It is respectfully requested that the remarks presented herewith be entered in this application, since they

are believed to clearly place the instant application in condition for allowance. In any event, the instant remarks are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments and remarks presented in the May 14, 2007 Official Action response and the remarks presented herewith, it is respectfully urged that the rejections set forth in the February 7, 2007 Final Official Action and maintained in the June 1, 2007 Advisory Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned at the phone number given below.

Respectfully submitted,  
DANN, DORFMAN, HERRELL AND SKILLMAN  
A Professional Corporation

By   
Robert C. Netter, Jr., Ph.D.  
PTO Registration No. 56,422

Telephone: (215) 563-4100  
Facsimile: (215) 563-4044